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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/773,351	01/31/2001	Daniel H. Macs	00.22US	5974

7590 09/10/2004

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EXAMINER
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JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/773,351

Applicant(s)

MAES ET AL.

Examiner

Shaojia A. Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 and 3-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

This Office Action is a response to Applicant's response (remarks/Arguments) filed June 23, 2004 wherein no amendment is filed, i.e., no claims are amended, cancelled, or newly submitted.

Currently, claims 1 and 3-20 are pending in this application.

Claims 1 and 3-20 are examined on the merits herein.

Applicant's remarks filed June 23, 2004 with respect to the rejection of claims 1 and 3-20 made under 35 U.S.C. 112 first paragraph for containing new subject matter which was not described in the original specification and claims, i.e., the recitation "integral with" of record stated in the Office Action dated March 23, 2004 have been fully considered and found persuasive to remove the rejection since the recitation "integral with" herein would be interpreted as "mixed with" or "a mixture of" or "combination with" according its plain and ordinary meaning. Therefore, the specification as originally filed does provide support for the recitations "mixed with" or "a mixture of" or "combination with". Therefore, the said rejection is withdrawn.

For the same reasons as discussed above, Applicant's remarks filed June 23, 2004 with respect to the rejection of claims 1 and 3-20 made under 35 U.S.C. 112 second paragraph for the use of the indefinite recitation, i.e., "integral with" of record stated in the Office Action dated March 23, 2004 have been fully considered and found persuasive to remove the rejection since the recitation "integral with" herein would be

interpreted as "mixed with" or "a mixture of" or "combination with" according to its plain and ordinary meaning. Therefore, the said rejection is withdrawn.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-4, 6-9, 11 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribier et al. (5,925,364, of record) in view of Sebag et al. (5,411,742, of record) for the same reasons of record in the previous Office Action March 23, 2004.

Ribier et al. discloses a cosmetic or dermatological composition comprising the ionic amphiphilic lipid such as the alkali metal salts of cholesterol sulphate in particular the sodium salt in amount of 2-6% by weight preferably 3-4% by weight (see col.3 lines 43-48 and 54-55, col.4 lines 12-15), salicylic acid (a known exfoliant) (see claim 18 at col.15 line 6), keratolytic agents (known exfoliants) (see col.5 line 36, claim 15 at col.14 line 49), fatty acids broadly (see col.4 line 60, claim 18 at col.15 line 5), and Centella asiatica extract (see col.4 line 64, claim 18 at col.15 line 8). The cosmetic or dermatological composition Ribier et al. is known to topically apply to skin.

Ribier et al. does not expressly disclose the employment of the particular fatty acid, linoleic acid, and cholesterol in the composition herein. The prior art does also not expressly disclose the amounts of an exfoliant in the composition herein.

Sebag et al. discloses a cosmetic or dermatological composition comprising the salts of cholesterol (see col.2 line 34), salicylic acid or its derivatives (known exfoliants) in amounts of 3-10% by weight (see abstract, col.3 lines 26-36), keratolytic agents (known exfoliants) (see col.6 line 66), the particular fatty acid, linoleic acid (see claim 10 at col.17 line 17), and cholesterol (see claim 8 at col.17 lines 5-6).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the particular fatty acid, linoleic acid, and cholesterol in the composition of Ribier and to optimize the effective amounts of an exfoliant in the composition herein to about 10% by weight.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the particular fatty acid, linoleic acid, and cholesterol in the composition of Ribier since fatty acids broadly and the particular fatty acid, linoleic acid, are known to be useful in a cosmetic or dermatological for of treating skin based on the prior art. Moreover, cholesterol is well known to be used a cosmetic or dermatological for of treating skin according Sebag. Therefore, one of ordinary skill in the art would have reasonably expected that combining the composition of Ribier and the composition of Sebag known useful for the same purpose, treating skin, in a composition to be administered would improve the therapeutic effect for treating skin.

Since all active composition components herein are known to be useful to treat skin, it is considered *prima facie* obvious to combine them into a single composition to form a third composition useful for the very same purpose. At least additive therapeutic effects would have been reasonably expected. See *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980).

Additionally, one of ordinary skill in the art would have been motivated to optimize the effective amounts of the alkali metal salts of cholesterol sulphate and an exfoliant in the composition because their amounts are known in the art and the optimization of known amounts of active agents to be administered is considered well within the skill of artisan. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

### ***Response to Argument***

Applicant's remarks filed June 23, 2004 with respect to this rejection made under 35 U.S.C. 103(a) as being unpatentable over Ribier et al. (5,925,364) in view of Sebag et al. (5,411,742) in the previous Office Action March 23, 2004 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

Applicants assert that "the formation of discrete layers of a lipid vesicle is precisely what occurs when the ionic lipid is mixed in the '364 preparation." and "The

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'364 preparation does not produce a mixture because the ionic lipids swell under the action of mixing to form discrete layers of a lipid vesicle which separates its contents from the other ingredients in composition, namely the outside media (e.g., the aqueous phase). Applicants also argue that "There is a stark contrast between the act of mixing and the act of producing a mixture" and "In none of the cited references does the act of mixing produce a mixture".

Applicants' assertion and argument are not found convincing. Again, Applicant is requested to note that that the instant claims are **not limited** to "the act of mixing produce a mixture" and in what orderly manner to form discrete layers of a vesicle dispersed in the aqueous phase. The instant claims merely recite a composition comprising a mixture of effective amounts of cholesterol sulfate or salts thereof, integral with or mixed with an exfoliant in a cosmetically or pharmaceutically acceptable vehicle. However, the features upon which applicant argue and assert, are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, it is irrelevant whether the reference includes those features or not.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Ribier et al. (5,650,166) for the same reasons of record in the previous Office Action March 23, 2004.

Ribier et al. discloses a moisturizing composition for the treatment of surface and deep layers of the skin clear comprising the instant ingredients such as cholesterol sulfate in the salt of alkali metal (including potassium) (see col.3 lines 64-67), N-acetylglucosamine (see col. 5, lines 59-67), the particular sterol, cholesterol (see col.3 line 60 and col. 6, lines 47-49), fatty acids, including linoleic acid (see col. 6, lines 44-46). Ribier' 166 further teaches the use of plant extracts (see col. 7, lines 5-8). The compositions of Ribier et al. may be emulsion, gel, lotion, and ointment forms (see col.7 lines 10-14).

Thus, the disclosure of Ribier et al. anticipates Claims 1 and 3-9.

### ***Response to Argument***

Applicant's remarks filed June 23, 2004 with respect to this rejection made under 35 U.S.C. 102(b) as being anticipated by Ribier et al. (5,650,166) in the previous Office Action March 23, 2004 have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as further discussed below.

Applicants agree that the arrangement in the '166 Ribier reference is not a "mixture" as one of ordinary skill in the art would understand it" and "Two ingredients that



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are separated from one another, as they are in the '166 Ribier by virtue of the vesicle formations cannot be a mixture or be integral with one another because they are not actually combined".

Again, Applicants' assertion and argument are not found convincing. As pointed out above, that the instant claims are not limited to what is the way or manner the ingredients of prior art combine or mix" and "the act of mixing produce a mixture" or in what orderly manner to form discrete layers of a vesicle dispersed in the aqueous phase. The instant claims merely recite a composition comprising a mixture of effective amounts of cholesterol sulfate or salts thereof, integral with or mixed with an exfoliant in a cosmetically or pharmaceutically acceptable vehicle. However, the features upon which applicant argue and assert, are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, it is irrelevant whether the reference includes those features or not, so long as the prior art discloses a composition comprising the same ingredients.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribier et al. (5,650,166) for the same reasons of record in the previous Office Action March 23, 2004.

The same disclosure of Ribier et al. (5,650,166) has been discussed in the 102(b) rejection set forth above.

The cited prior art does not expressly disclose that the amount of the each instant ingredient.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the amount of the known particular agents taught in Ribier et al.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the amount of the known particular agents taught in Ribier et al. since the determination or optimization of amounts of known cosmetic agents, is considered well within conventional skills in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Claims 10-12 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribier et al. (5,650,166) further in view of Subbiah (6,150,381) and Ichinose et al. (5,702,691) for reasons of record stated in the Office Action dated March 23, 2004.

The claims are directed to compositions further comprising sclareolide and white birch extract.

The same disclosure of Ribier et al. (5,650,166) has been discussed in the 102(b) rejection set forth above.

The cited prior art does not expressly disclose the employment of sclareolide and white birch extract.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to add or employ sclareolide and white birch extract in the composition of Ribier et al.

Subbiah teaches the use of sclareolide in topical formulations, padicularly for cne (see abstract). Sclareolide is taught in combination with other ingredients (see col. 5, line 6 through col. 7, line 12). Subbiah teaches that sclareolide has antimicrobial activity that is useful in the treatment of acne (see col. 4, lines 45-65).

Ichinose teaches that white birch extracts are known anti-inflammatory agents (see col . 5, lines 4-13).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the compositions of Ribier '166 by the addition of sclareolide for its anti-acne properties as taught by Subbiah and by the addition of white birch extract for its anti-inflammatory properties as taught by Ichinose. The motivation for the modification comes from the benefit of such propedies in formulating cosmetic compositions. The missing ingredients have art-recognized suitability for the intended purpose of formulating cosmetic compositions. The selection of a known material based

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on its suitability for its intended use has been determined to be prima facie obvious. See *Slhclair & Carroll Co. F. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945)., *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960); and MPEP 2144.07.

### ***Response to Argument***

Applicant's remarks filed June 23, 2004 with respect to the rejection of Claims 13-20 made under 35 U.S.C. 103(a) over Ribier et al. (5,650,166) have been fully considered but are not deemed persuasive as to the nonobviousness of the claimed invention over the prior art as discussed above.

In particular, note that the instant claims are not limited to the particular form of mixture, and moreover, Ribier et al. teaches the compositions therein for topical use in emulsion, gel, lotion, and ointment forms.

Applicant's argument that the cited Ribier et al. (5,650,166) does not teach NADG directly added to a vehicle, is not found convincing. The instant claims are not limited to specific method in a specific method steps for the preparation of the instant composition. Therefore, it is irrelevant whether the reference includes those features or not.

Further, Applicant's one Example shown in the specification at pages 8-10 herein have been fully considered but are not deemed persuasive as to the nonobviousness and/or unexpected results of the claimed invention over the prior art for the reasons below. Example 1 provides no clear and convincing evidence of nonobviousness or unexpected results over the cited prior art since there is no comparison to the same present. Therefore, the evidence presented in specification herein is not seen to be

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clear and convincing in support the nonobviousness of the instant claimed invention over the prior art.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/424,616 for reasons of record stated in the Office Action dated March 23, 2004.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the copending application and the instant application are drawn to a skin/cosmetic composition containing cholesterol sulfate, fatty acids, and a sterol (such as cholesterol) and methods employing the compositions.

Thus, the copending Application No. 10/424,616 and the instant claims are seen to substantially overlap.

Thus, the instant claims are seen to be obvious over the all claims of copending Application No. 10/424,616.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Note that Applicants did not argue this provisional obviousness-type double patenting rejection in the remarks filed June 23, 2004.

In view of the rejections to the pending claims set forth above, no claims are allowed.

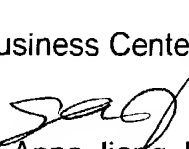
**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703.872.9307.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
S. Anna Jiang, Ph.D.  
Patent Examiner, AU 1617  
August 25, 2004

SHAOJIA ANNA JIANG  
PATENT EXAMINER  
9/7/04